
MTN-016 Data Communiqué #3

13 August 2013

This is official study documentation for MTN-016. Please circulate it among relevant staff for their review, print it, and place it in your MTN-016 SSP Manual in the Data Communiqués section.

This document is considered part of the MTN-016 SSP manual.

UPDATES

1. Infant Vaccination Log (IVL-1)

A new Infant Vaccination Log was created so that sites can document all vaccinations administered to infants using vaccination codes (vaccination codes are located in the Data Management Section of the SSP and are also posted on the MTN-016 Atlas web-page in the “Other Documents” section). Vaccinations administered to infants must no longer be recorded on the Infant Concomitant Medications Log. The new IVL is provided with this communiqué and has also been added to the CRF Newborn/Initial Visit 1 packet and the individual infant CRFs posted on Atlas. Sites may begin using the new form immediately. However, sites are expected to use the new IVL no later than **27 August 2013**.

2. Infant Concomitant Medications Log (CM-1)

The instructions on the Infant Concomitant Medications Log have been updated to include a reminder that vaccinations can no longer be recorded on the CM Log; all infant vaccinations should now be recorded on the Infant Vaccination Log. The updated CM Log is provided with this communiqué and has also been added to the CRF Newborn/Initial Visit 1 packet and the individual infant CRFs posted on Atlas.

3. New Enrollment and Retention Reports

In addition to the cumulative Enrollment and Retention Reports, which show the overall enrollment and retention for all participants in MTN-016, there are now Enrollment and Retention Reports for woman and infants who have come from MTN-020. These new reports have been posted to the MTN-016 Atlas home page:

<https://atlas.scharp.org/cpas/project/MTN/016/begin.view>

Access to the reports is not restricted; therefore, you do not need an Atlas username and password to view them.

CLARIFICATIONS

None.

REMINDERS

1. Do Not Print CRFs on Colored Paper

Sites should no longer use colored paper to print CRFs. Certain colors of paper do not transmit well, thus making it difficult for DataFax to read the data from those CRFs into the database. Please use white paper only when printing CRFs.